EXHIBIT 51

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc., Zachary T. Bentley, and T. Mark Jones v. Abbott Laboratories, Inc.*, No. 07-CV-11618-PBS	)	Magistrate Judge Marianne B. Bowler

EXPERT REPORT OF JAMES W. HUGHES

I. Introduction

1. I am the Thomas Sowell Professor of Economics at Bates College. I prepared this report at the request of counsel for Abbott Laboratories Inc. ("Abbott") to review and evaluate the Relator's liability and damage calculation in this matter as proposed by its expert Dr. Mark Duggan.

2. In my opinion Dr. Duggan's calculation of damages is fatally flawed in both concept and execution. First, as he admits, his is not a damage calculation, but only a calculation of a "difference" in government expenditures. His concept of the but-for world does not consider the evidence in the record of the likely consequences were state and federal agencies to adopt the alternative payment methodologies he proposes. He ignores, for example, the testimony of state officials and other evidence that reimbursements like the ones he proposes would require increases in dispensing fees. He ignores the fact that when the government made changes to the Medicaid reimbursement system to reduce reimbursements and/or to address the issues that are the subject of this litigation, the changes adopted bear no resemblance to his alternative payment method. A valid vision of the but-for world should take into account the likely consequences for, and reactions by, market participants. Dr. Duggan's does not do this in my opinion.

3. Even if one were to accept Dr. Duggan's but-for world, his method of calculating damages is in my opinion fatally flawed. For Medicaid, he bases his national damage estimates on incomplete claims data for only fifteen states. The fifteen states he chose are not a representative sample of the population of states. He ignores data on other states that is presumably available from the government. He uses extrapolation to estimate damages to 34 other states, introducing needless error into his estimates. For

these and other reasons, the resulting estimates are in my opinion inaccurate and unreliable. Dr. Duggan also fails to consider the consequences of his proposed reimbursement method on patient access. He ignores substantial evidence showing that concern over inadequate dispensing fees and the potential effects of reducing reimbursements on patient access were, in fact, major factors in shaping states' reimbursement policies.

4. By using flawed, incomplete, unrepresentative data, and using these data to calculate extrapolations that are flawed and unrepresentative of the but-for world, it is my opinion that Dr. Duggan's damage methodology and resulting estimates are inaccurate and unreliable.

II. Background and Experience

5. I specialize in the fields of Industrial Organization; Law and Economics; Health Economics; Environmental Economics; and Labor Economics. I earned my M.A. in Economics, from Boston University in 1978, and my PhD in Economics from The University of Michigan in 1987. I joined the faculty of Amherst College in 1987 and the faculty of Bates College in 1992. In 2005, I was named the Thomas Sowell Professor of Economics.

6. I have experience in the economic analysis of competition issues in the pharmaceutical industry, including injury and damage issues in the AWP litigation. I submitted a report in an AWP action regarding certain injectable drugs brought by the Attorney General of Connecticut.[1] I also submitted a report in the AWP actions in the

[1] *State of Connecticut v. Aventis Pharmaceuticals*, Docket X07 CV03-0083299 S (CLD).

states of Montana and Nevada.[2] Outside of the AWP actions, I have testified and/or offered reports in matters involving the prescription pharmaceuticals Cipro, Cardizem, Rezulin and Procardia XL. I have also testified in a class certification matter involving the prescription benefit manager Medco Health Systems. My curriculum vita is attached as Exhibit 1, and a list of cases in which I have provided testimony appears as Exhibit 2. I am being compensated at a rate of $575 per hour.

III. Basic Allegations and My Assignment

7. The Relator alleges that Abbott reported "false, fraudulent and inflated drug prices"[3] to the pricing compendia such as First Data Bank. The Relator further claims that such allegedly false reporting caused agencies to pay "inflated"[4] reimbursements to Abbott's customers.

8. The Relator also claims that Abbott consciously manipulated the so-called "spread" between the AWP (used in computing some government reimbursements) and the price actually paid by Abbott customers. This alleged manipulation operated by either indirectly raising the AWP, or lowering the customer's purchase price, or both, thus increasing the customer's profit, not Abbott's profit, from the transaction. According to the complaint, Abbott allegedly profited from this "scheme" by increasing sales of its products.[5]

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[2] In Re Pharmaceutical Industry Average Wholesale Price Litigation, in the matters of: *State of Nevada v. American Home Prods. Corp., et al.*, 02-CV-12086-PBS; and *State of Montana v. Abbott Labs., Inc., et al.*, 02-CV-12084-PBS, MDL NO. 1456, Master File No. 01-CV-12257-PBS.

[3] U.S. ex rel Ven-a-Care of the Florida Keys v. Abbott Laboratories, Inc., Complaint for Violation of the False Claims Act, Civil Action No. 00 CV 10698 MEL at ¶3. [Hereafter cited as "Complaint"] at ¶3.

[4] Id. at ¶3

[5] Id. at ¶3.

9. I have been asked by counsel for defendant Abbott to evaluate the Relator's liability theory and damage claims. I have been asked to review the methodology employed by the Relator's expert for estimating the injury, damages, and penalties allegedly incurred by Medicaid as a result of the alleged wrongful actions, and to offer my opinion as an economist about the opinions, methodology and accuracy of the resulting estimates. A list of materials I considered is attached as Exhibit 3.

IV. Factual Background

A. Nature of the Drugs at Issue

10. Pharmaceuticals are generally classified as either "brand-name" (i.e., patent-protected) drugs, or "generic," also referred to as multisource drugs. The drugs at issue in this litigation are generic antibiotic pills. For the time period at issue in this matter, all patent protection for these drugs had expired. Since patent expiry, many companies have entered and exited the manufacture of erythromycin. As a generic drug, any company that can meet the FDA's standards for bioequivalence may produce erythromycin. According to the Orange Book, 20 different companies today produce various forms of erythromycin.[6]

11. In the case of generic drugs, each firm's drugs are functionally and literally identical to the drugs of every other manufacturer. Markets for generic drugs tend to be quite competitive. As such, day-to-day prices change with the forces of supply and demand. If one or more manufacturers face supply issues, prices in the market may rise in response. Unforeseen emergencies such as natural disasters can lead to increases in

[6] Electronic Orange Book, accessed online at www.fda.gov/cder/ob/docs/queryai.

demand and price. Drugs may be sold to different customers at different prices depending on market and demand circumstances.

B. The Use of List Prices

12. Firms in many different industries use list prices as both actual transaction prices and a starting point for negotiations with larger customers, regular customers, and/or new customers whose business they are trying to win. Such a practice allows firms to charge the list price to "spot" customers, who may buy either small quantities of the drug, or on a one-time basis. Larger, regular customers or buying groups can negotiate lower prices, the size of the discounts correlating generally with the importance of the customer. Price discounting in this way helps firms compete for business by rewarding their best customers, and/or attracting new customers with lower purchase prices.

13. It is well established in the economics literature that monopolistic collusion is facilitated when firms can observe each other's actual selling prices.[7] Competitive price-cutting is, on the other hand, greatly encouraged when, as in this case, firms can keep their discounting practices confidential. A leading text on competitive strategy, discussing how competitors might facilitate price collusion, states:

> When sales transactions are "public," deviations from cooperative pricing are easier to detect than when prices are secret. ... [I]n many industrial goods markets, prices are privately negotiated between buyers and sellers, so it may be difficult for a firm to learn whether a competitor has cut its price. Because retaliation can occur more quickly when prices are public than when they are secret, price cutting to steal market share is likely to be less attractive, enhancing the chances that cooperative pricing can be sustained.

[7] The antitrust economics literature is replete with schemes would-be colluders have employed to force disclosure of transaction prices. Reporting prices to trade associations, basing-point pricing and the like are recognized as classic methods of facilitating collusion through the use of published transaction prices.

When sellers can keep their sales prices confidential, competition is enhanced:

> Secrecy is a significant problem [for colluders] when transactions involve other dimensions besides a list or invoice price, as they often do in business-to-business marketing settings. ... [A] manufacturer...that wants to steal business from a competitor...can cut its "net price" by increasing trade allowances to retailers or by extending more favorable credit terms. Because it is often more difficult to monitor trade allowance deals or credit terms than list prices, competitors may find it difficult to detect business-stealing behavior, hindering their ability to retaliate.[8]

14. In short, offering discounts from list price to gain and keep customers is more successful when the discounts are kept confidential than when they are done publicly. Publicly announced reductions in selling price may be quickly matched by competitors, making them an ineffective method for gaining or keeping customers. Publicly announced discounts are more costly to producers as the firm's other customers will demand similar discounts. As lower prices for manufacturers' drugs ultimately benefits consumers, economists believe that such discounting should be encouraged rather than discouraged.

15. Professor Fiona Scott-Morton examined the effect on drug prices of the Medicaid "Most-Favored Customer" (MFC) requirement contained in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90).[9] An MFC clause requires that all customers with such a clause in their contract must receive the lowest price given to any one

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[8] David Besanko, David Dranove, and Mark Shanley, *The Economics of Strategy,* 2d ed., (New York, John Wiley & Sons, 2000) at 305-306.

[9] Fiona Scott-Morton, "The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules," Rand Journal of Economics, v.28 n. 2, Summer, 1997 at 269-90, and "The Interaction between a Most-Favored-Customer Clause and Price Dispersion: an Empirical Examination of the Medicaid Rebate Rules of 1990," Journal of Economics and Management Strategy, v.6 n. 1, Spring 1997 at 151-174.

customer. An MFC clause is thus identical in effect to the public disclosure of pricing discounts, as any discount must be applied to all covered customers. Professor Scott-Morton found that drug selling prices actually rose somewhat after the passage of OBRA 90. Discounting became more expensive for firms, and firms thus did less of it. She also found that the dispersion of selling prices became less, again indicating less discounting. Professor Scott-Morton concluded that the MFC requirements of OBRA 90 actually caused the prices paid by some pharmaceutical customers to rise.[10]

16. Abbott's Pharmaceutical Products Division (PPD) sold the majority of these drugs to wholesalers. PPD published a wholesale acquisition cost (WAC) for each of the subject NDCs, and some customers purchased the subject NDCs at these WACs. Sales at WAC yielded significant profits for Abbott. Other customers meeting purchase requirements qualified for contract prices below WAC. Abbott's profit or loss on its sales of erythromycin would depend only on the price paid to Abbott by the wholesaler or pharmacy and the quantity sold at that price.

17. Abbott's profit or loss on these sales did not depend on whether the pharmacies dispensing its drugs would be reimbursed by Medicaid, private insurance, or cash payment. Pharmacies dispensed erythromycin to patients, receiving payment for these prescriptions from third-party payers, Medicaid, or the patients' cash payments. Third party payer reimbursements were made to the pharmacies, not to Abbott. The Relator claims that Abbott profited from the alleged AWP manipulation scheme by increasing its sales.[11] Dr. Duggan's report presents no evidence to support this allegation.

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[10] Scott-Morton, Rand Journal at 269.
[11] Complaint at p. 2, ¶3.

18. Abbott periodically announced list price changes for erythromycin. Because of the nature of the market for erythromycin, these list price changes occurred only every two to four years. The magnitude of these changes were also small, such that over the period covered by this action, Abbott's list price changes did not keep pace with the relevant rate of inflation.[12]

V. Dr. Duggan's Damages Calculations Are Inaccurate And Unreliable As They Are Based On A Fanciful and Untenable Vision of the But-For World

19. When estimating damages, an economist compares the price actually paid with the price that would have been paid in the "but-for" world, that is, the world absent the alleged wrongful behavior.[13] Any valid vision of this but-for world must be based on the available evidence as to the situation that would actually exist in the world without the alleged wrongdoing. This evidence must include not only the alleged but-for price, but also include an assessment of actors' anticipated responses to the incentives, rewards, and costs imposed by the changed circumstances. To do otherwise will result in an inaccurate and misestimated "but-for price" that will yield inaccurate and unreliable estimates of alleged damages.

20. Dr. Duggan does not conduct such an economic analysis. His characterization of the but-for world is one-dimensional, divorced from the realities of the market he purports to analyze. He calculates a "...difference between (1) what the federal government reimbursed for certain pharmaceutical products provided to Medicaid recipients during the 1994Q1 to 2008Q1 period and (2) what the federal government

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[12] The direct price of Abbott erythromycin increased by only around ten percent over the entire fourteen year period of this action. See Expert Report of Mark G. Duggan Ph.D., March 27, 2009, at Figures 1 and 2 [hereafter cited as "Duggan Report"].

[13] See Roger Blair and William Page, "Speculative Antitrust Damages," 70 Wash. L. Rev., April 1995.

would have reimbursed for the same products during the same time period if prices reflective of the actual prices at which Abbott was transacting business had been used for the AWP, WAC, and Direct Price of Abbott products."[14] He then assumes that Medicaid reimbursements would have been reduced to the payment levels utilized in his "difference" calculation.[15] Everything else, including provider participation in the programs, fees paid to compensate pharmacies for the cost of dispensing the drug and other factors are assumed to remain constant. Other influences, such as the need to meet Federal mandates to ensure access in the Medicaid program, the information available to government officials, or the presence of Federal Upper Limits ("FUL"), Maximum Allowable Costs ("MAC"), or other reimbursement methodologies willingly negotiated between pharmacies and state Medicaid agencies are not taken into account in Dr. Duggan's analysis. All of these factors would be an integral part of any viable and accurate economic assessment of alleged damages.

21. As I will discuss in more detail below, by ignoring these very real economic factors in his analysis, Dr. Duggan's calculations do not constitute a damage analysis in this matter. Notably, he himself never uses the word "damage" in his report in this matter,[16] and resists characterizing his calculation as "damages" caused by Abbott's alleged misconduct at deposition,[17] preferring instead to refer to his calculations as merely a "difference" in government payments between the actual and his but-for

[14] Duggan Report at ¶1.
[15] Id. at 8-9.
[16] Id.
[17] Deposition of Mark G. Duggan, PhD., vol I, July 14, 2008 at 37:13-47:21 and 76:20-79:6.

world.[18] He says that his calculations are merely "one input into the calculation of damages."[19] Dr. Duggan ignores a vast amount of evidence and testimony in this matter that speaks directly to the accuracy of his characterization of the but-for world. Dr. Duggan admits that he uses assumptions in his analysis that he has not verified.[20] He did not ask for, nor did the Relator provide to him other claims data that the Government presumably has in its possession.[21] Instead, his alleged damage estimates are based on extrapolations that are themselves flawed. He ignores the fact that, almost eight years after the filing of this complaint, after many successful and unsuccessful attempts to reform drug reimbursements under Medicaid, no state or Federal program has replaced the reimbursement system at issue here with a system with the same or similar characteristics to the one proposed by Dr. Duggan. He ignores the fact that, even today CMS continues to approve state Medicaid implementation plans containing the same allegedly flawed reimbursement system that gave rise to the current litigation.[22]

A. Medicaid

22. Dr. Duggan's damage estimates for Medicaid are tainted by reliance on a but-for world that is at odds with the record in this matter. Dr. Duggan's but-for world relies on

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[18] While Dr. Duggan uses the term "difference" rather than "damage" to describe his calculations, it is my understanding that the Relator is using his calculations as their estimate of damages in this matter. For this reason, I refer to Dr. Duggan's calculations as damage or alleged damage calculations.

[19] Id. at 41.

[20] Duggan DOJ Deposition at 28-29, 86-88, 193-96, 674-82, and 858-65.

[21] Duggan Ery Deposition, April 17, 2009 at 101.

[22] According to the CMS website, all but two states' reimbursement systems are based on AWP in some way. U.S. Health and Human Services, Centers for Medicare and Medicaid, "Medicaid Prescription Reimbursement Information by State—Quarter Ending December, 2008," accessed online at http://www.cms.hhs.gov/Reimbursement/Downloads/MedicaidPrescriptionReimbursementInformationbyStateDecember2008.pdf.

the assumption that there would have been no political or regulatory impediments preventing Medicaid officials from immediately and unanimously adopting reimbursement policies based on his calculation of average acquisition cost. Dr. Duggan also assumes that in the but-for world, Medicaid dispensing fees would not increase to compensate for the loss in revenue to pharmacies from the reduction in reimbursement. In addition, his but-for world assumes that all states are the same, in spite of the fact that Medicaid implementation plans are designed and approved on a state-by-state basis. Nevertheless, Dr. Duggan assumes that states all face the same challenges in ensuring access to care, and all states respond in the same way to such challenges and obstacles. As I will show in the following pages, all of these assumptions are at odds with the record in this matter. By ignoring these factors in constructing his but-for world, Dr. Duggan has, in my opinion, greatly overstated the likely damages resulting from the alleged wrongful behavior in this case.

1. What Information Did Medicaid Officials Have About Pharmaceutical Pricing Practices?

23. An accurate assessment of the but-for world is essential to a valid damages analysis. What information government officials had about pharmaceutical prices and when they had it is highly relevant to characterizing the but-for world. AWP has never been equal to average acquisition price. Dr. Duggan's damage assessment assumes the government never knew this fact over the past forty plus years. If, conversely, many or most government officials were fully aware that AWP does not equal average acquisition cost, and formed their reimbursement systems in full cognizance of that fact, a very different but-for world and very different damage assessment would result.

24. Evidence will be presented at trial as to what government officials knew or did not know about pharmaceutical pricing practices and how these affected reimbursements. The facts and testimony cited below are the result of my nonexhaustive review of the record. The point is that whatever the facts turn out to be from trial testimony, they are relevant to the accurate assessment of damages, yet Dr. Duggan has ignored such factors in his damage calculation.

a. Government Reports

25. A long history of reports both by, and commissioned by, government agencies, testimony before Congress and legislatures, filings in legal challenges and other public actions shows that government officials at all levels had considerable information available to them that AWP was not a selling price and that WAC did not include discounts and rebates. This history now stretches back over 40 years.

26. In 1968, the U.S. Department of Health, Education and Welfare (HEW) published a report on prescription drugs.[23] The task force noted,

> ...wholesalers, retailers, hospitals and government agencies often pay markedly different prices for the same drug and dosage form.[24]

and,

> The *Red Book* and Blue Book do not reflect actual manufacturers' prices to wholesalers and retailers which are determined by the amounts of various kinds of discounts.[25]
>
> The catalog [list] price constitutes an 'umbrella' beneath which the company can maneuver against competing products.[26]

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[23] U.S. Department of Health, Education and Welfare, "Task Force on Prescription Drugs: The Drug Makers and Drug Distributors," U.S. Government Printing Office, 1968.
[24] Id. at 31
[25] Id.
[26] Id. at 33

27. In 1974, an HEW Federal Register Notice read,

> Red Book data, Blue Book data (i.e. AWP) and other standard prices...were frequently in excess of actual acquisition cost.[27]

28. A 1977 HCFA action memo to states noted that

> [T]he Department is not convinced that those states which continue to reimburse at average wholesale price or wholesale invoice cost have made a real effort to approach actual acquisition cost.[28]

29. In 1984, a report from the Office of the Inspector General for the Department of Health and Human Services found that pharmacies purchased most drugs at an average price 15.9 percent below AWP,[29] while actual prices were as much as 42 percent below AWP. The report noted that AWP was not "...even an adequate estimate of the prices pharmacies are generally paying for their drugs. AWP represents a list price and does not reflect several types of discounts."[30] The report also noted that "Within the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price."[31]

30. This same report shows an AWP of $21.95 for EES (Abbott brand erythromycin) against a 70th percentile price of $16.49 per the audit conducted by the OIG. This variance constitutes a spread of 133.11 percent as calculated by the Relator in its complaint.[32]

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[27] U.S. DHEW, "Proposed Reimbursement of Drug Cost," 39 Fed. Reg. 230 at 41,480, November 27, 1974.
[28] HCFA Action Transmittal 77-113 (MMB) —Formula for Determining EAC for Drugs at ¶28,714.
[29] HCFA Action Transmittal, No. 84-12, September, 1984, "Medicaid—Limitation of Payment for Drugs" at ¶34,157 p. 10,193.
[30] Id. at p. 10,206.
[31] Id. at p. 10,193.
[32] Id. at p. 10,203.

31. In 1987, the Federal Upper Limit program (FUL) was established for Medicaid.[33] This program was enacted to assure the Medicaid program a uniform price nationally for multisource drugs.[34] The FUL regulations allowed a markup of 150 percent above the "least costly therapeutic equivalent." This margin was allowed, in part, to ensure that pharmacies would not "...lose money on acquisition costs."[35]

32. A 1989 U.S. Senate staff report concluded,

> There are two markets in the U.S for most big selling prescription drugs: a price competitive market characterized by deep discounts off of list price, and a high-priced market, where retail customers, Medicare and Medicaid purchase their prescription drugs.[36]

The report also found that the Veterans' Administration received an average discount of 41 percent off AWP for single source drugs and 67 percent off of AWP for multiple source drugs. In the private sector, the report noted that hospitals, managed care entities and nursing home that have contracts with wholesalers receive discounts of up to 99 percent off of AWP.[37]

33. Information disclosed at a 1992 Congressional hearing showed discounts off of AWP for some of the drugs at issue of 57 to 86 percent.[38] This transcript shows that discounts from AWP on the subject drugs of this litigation were similar to or exceeded the average discounts reported in other government reports.

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[33] Federal Register, "Part 447: Payments for Services" v. 52 n. 147 July 31, 1987 at 28557-28558.
[34] A FUL could be adopted for a multisource drug once there were three therapeutically equivalent drugs in the market. CMS website at http://www.cms.hhs.gov/Reimbursement/05_FederalUpperLimits.asp
[35] Fed. Reg. 28648 July 31, 1987.
[36] United States Senate, Special Committee on Aging, "Prescription Drug Prices: Are We Getting Our Money's Worth?" August, 1989 at 3.
[37] Id. at 11.
[38] U.S. House of Representatives, 102d Congress, Subcommittee on Health and the Environment, "Prescription Drug Rebate Program," Hearing, July 31, 1992, 303-304.

34. A lengthy article on the divergence between AWP and acquisition costs appeared in the June 10, 1996 issue of *Barron's* newspaper. Entitled "Hooked on Drugs," the article found acquisition costs for multisource drugs 60 to 85 percent below AWP.[39] This article was quoted in the 1997 OIG report on generic drug pricing.[40]

35. In this 1997 report, the OIG conducted a study based upon invoices collected from pharmacies with the stated purpose of calculating the difference between AWP and actual acquisition costs. The OIG concluded "we have determined that there is a significant difference between pharmacy acquisition cost and AWP."[41] Specifically, the OIG "...estimated that pharmacies pay an average of 42.5 percent less than AWP for drugs sold to Medicaid beneficiaries."[42]

36. Also in 1997, the OIG reported that "Medicare allowed between 2 and 10 times the actual average wholesale prices..."[43] Subsequent to this report, President Clinton addressed Medicare and Medicaid reimbursement in his radio address in December 1997,

> Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system... These overpayments occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price for drugs. Few doctors actually pay the full sticker price. In fact, some pay just one-tenth...[44]

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[39] Barron's Newspaper, "Hooked on Drugs" June 10, 1996.
[40] U.S. HHS, Office of the Inspector General, "Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products," August, 1997 at 1-2.
[41] Id. at 5.
[42] Id. at 4.
[43] U.S. HHS Office of Inspector General, "Excessive Medicare Payments for Prescription Drugs," December, 1997 at 8.
[44] President William Clinton, Radio Address 12/13/97, John T. Woolley and Gerhard Peters, *The American Presidency Project* [online]. Santa Barbara, CA: University of California (hosted), Gerhard Peters (database). Available from World Wide Web: http://www.presidency.ucsb.edu/ws/?pid=53703.

b. State Medicaid Officials' Testimony

37. In the eight years since the filing of this action, in deposition and trial testimony in this and related matters, state and federal officials have spoken to the extensive knowledge at various levels of HCFA (later CMS) and state agencies that AWP was not a sales price. I note that Dr. Duggan has testified that while he has "seen" some of the testimony of state Medicaid officials, he has not conducted a review of such testimony for use in writing his report, despite the obvious relevance of such testimony to the matter at hand.[45]

38. For example, a Florida Medicaid official testified that he knew by as early as 1987 that "everyone gets a discount" from AWP,[46] and by 1990 knew that AWP was not a "reasonable indicator" of sales price for generic drugs.[47] In Ohio, Robert Reid of the Department of Human Services testified that he was aware that "nobody paid AWP" going back to 1969, and that the differences between AWP and acquisition cost varied greatly by drug.[48] In Delaware, a 1996 study showed pharmacies purchasing generic drugs at an average discount from AWP of over 60 percent.[49] A representative from New Jersey Medicaid testified that

> New Jersey, the state, has always had an understanding of what AWP was. We didn't operate within a vacuum. There were always ongoing discussions, and...going back to the '90s there were ques – even back in

[45] Duggan DOJ Deposition at 679-680.
[46] Deposition of Jerry Wells, Florida State Medicaid, December 15, 2008 at 69-70.
[47] Id. at 340-341.
[48] Deposition of Robert Reid, Ohio Department of Job and Family Services, December 15, 2008 at 101-104.
[49] Deposition of Cynthia Danemark, Delaware Division of Medicaid and Medical Assistance, December 9, 2008 at 142-145. Ms. Danemark also testified that she did not think there was any predictable relationship between AWP and acquisition cost in her experience. Id. at 269. She knew that AWP was not a valid basis for reimbursement back to 1988. Id. at 311-312.

> the '80s there were questions regarding AWP, its value with respect to establishing a benchmark for reimbursement.[50]

39. I have found similar references in the deposition testimony of at least nine other state officials,[51] all testifying to the fact that it was known in their particular state agencies that AWP was only a starting place for negotiations, that discounts, sometimes deep discounts from AWP were common. Several of these officials spoke of their awareness of these facts in the context of trying to change reimbursement systems, and/or reasons why they decided against such changes.

40. The accounting firm of Myers and Stauffer conducted studies of drug acquisition costs in the Medicaid program on behalf of both state Medicaid agencies and the Office of the Inspector General of the Department of Health and Human Services. Many state Medicaid agencies conducted these studies because, in the words of one such study conducted 22 years ago in Connecticut, "...the federal government is increasingly emphasizing controlling Medicaid costs by the use of more conservative estimates of estimated acquisition cost."[52] Myers and Stauffer conducted around twenty such studies on pharmacy acquisition costs from 1987 to 2001, some covering multiple states. A

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[50] Deposition of Edward Vaccaro, New Jersey Department of Human Services, December 3, 2008 at 638.

[51] Deposition of Harry Sullivan, Director of Pharmacy Services, TennCare, March 12, 2008; Deposition of Kevin Gorospe, California Department of Human Services, March 19, 2008; Deposition of Cody Wiberg, Minnesota Department of Human Services, March 14, 2008; Deposition of Sandra Kramer, Michigan Medical Services Administration, March 25, 2008; Deposition of Jerry Dubberly, Georgia Department of Community Health, December 15, 2008; Deposition of Benny Ridout, North Carolina Department of Health and Human Services, December 5, 2008; Deposition of James Parker, Illinois Department of Healthcare and Human Services, November 18, 2008; Deposition of Jesse Anderson, Oregon Department of Human Services, December 16, 2008; Deposition of Mary Terrebonne, Louisiana Department of Health and Hospitals, November 7, 2008.

[52] Myers & Stauffer, "A Survey of Costs of Dispensing Prescriptions and Estimated Acquisition costs in the State of Connecticut," February, 1987 at 53.

summary of these studies shows that Myers and Stauffer found that for multisource drugs, there were discounts from AWP ranging from 41 percent to over 80 percent.[53] The commissioning of these studies indicates not only that many state Medicaid officials were aware of the divergence between AWP and pharmacy acquisition costs, but that they were also seeking to do something about it. I note that Dr. Duggan relied on Myers and Stauffer for support in understanding state Medicaid figures, but made no inquiries concerning the development or implementation of state reimbursement systems.[54]

41. Finally, since 1991, Abbott has been reporting to the Federal government prices—the Average Manufacturers' Price (AMP)[55] required by the Medicaid Rebate Act—that are close to the prices that Dr. Duggan suggests Abbott should have been reporting. Exhibit 4 shows a comparison of the AMP reported quarterly to CMS and Dr. Duggan's version of average acquisition cost. Thus, contrary to Dr. Duggan's assumption, Abbott was in fact reporting "more truthful" prices to the Federal government on a quarterly basis. Furthermore, because of the divergence between AWP and AMP, the Federal government as well as the states had drug-by-drug information showing that AWP was not in fact a selling price.

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[53] Myers & Stauffer, "A Survey of Acquisition Costs of Pharmaceuticals in the Commonwealth of Kentucky," November, 2001 at Table B.1; Myers & Stauffer, "A Survey of Acquisition Costs of Pharmaceuticals in the State of Arkansas," June 2001 at Table B.1; See also "Pharmacy Final Reports Related to Dispensing and Acquisition Costs Produced by Myers and Stauffer," Exhibit 7, Deposition of Tracy Allan Hansen, December 10, 2008.

[54] Duggan Ery Deposition at 11-12.

[55] The term average manufacturer price means the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. 42 U.S. C. 1396r-8.

42. Dr. Duggan's but-for world acknowledges none of this. He fails to state what his assumptions are regarding these factors. The U.S. DHEW first examined the issues with Medicaid reimbursements over 40 years ago. Over time the evidence shows that these issues were a subject of interest at many levels of government. State agencies had specific and detailed information from a number of sources that AWP was higher than the pharmacy acquisition cost for prescription drugs.

43. Dr. Duggan's damage calculations are predicated on a but-for world where the extant reimbursement method is the result of government ignorance, rather than deliberate government policy. Dr. Duggan's but-for world assumes that the government would have based reimbursements on his estimate of average acquisition cost once they learned that AWP was not equal to acquisition cost. Even a cursory examination of evidence over the past 40 years demonstrates that the government had copious information that AWP was not acquisition cost, yet the reimbursement method did not change.

44. A valid damage methodology in this matter would not simply assume government ignorance of the facts. A valid methodology would need to consider the information available to government officials at various points in time, acknowledge attempts to change the reimbursement method in light of this information, and why government agencies or the Congress rejected these alternatives. Dr. Duggan does none of this.

2. Dr. Duggan's Methodology Wrongly Focuses On Ingredient Costs In Isolation, Rather Than Focusing On The Total Reimbursement To Pharmacies

45. Reimbursement methodologies varied by state and over time. One common model for Medicaid ingredient cost reimbursements to pharmacies during this period was

to set reimbursement equal to the lesser of 1) AWP minus a percentage ("scaled AWP"); 2) the pharmacy's usual and customary charge (U&C); 3) the state MAC; or 4) the FUL price. A dispensing fee is added to each of these ingredient cost reimbursements except U&C. The dispensing fee is intended to cover all of the pharmacy's costs, including the cost of storing, measuring, and delivering the prescription.

46. It was widely reported that the actual cost of filling a prescription at a pharmacy generally exceeded the Medicaid dispensing fees. The accounting firm of Myers and Stauffer conducted a total of 47 studies of dispensing fees, pharmacy dispensing costs and/or pharmacy acquisition costs between 1987 and 2007.[56] The Myers and Stauffer surveys showed that state Medicaid dispensing fees were often lower than the actual average costs of filling prescriptions in the states. The Myers and Stauffer cost surveys were primarily focused on the costs of filling prescriptions for patient administered drugs like the ones at issue in this matter.

47. It is important to note that the Myers and Stauffer reports often explicitly recognized the fact that ingredient cost reimbursement above acquisition cost made up for deficiencies in the dispensing fee payments for both private and public payers. A June 2002 Myers and Stauffer study for the State of California found that,

> Findings from this study indicate that the current pharmacy ingredient reimbursement rate of AWP less 5% provides payments in excess of the costs actually incurred by California pharmacies in acquiring pharmaceutical products for Medi-Cal recipients. In fact, the acquisition cost study findings indicate that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately $10. *These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to*

[56] Deposition of Tracy Allen Hansen, 12/10/2008, at Ex. 7.

> *fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement.* [emphasis added][57]

A second 2002 report specifically on dispensing fees in California states,

> The Department's current pharmacy dispensing fee is below the average cost of dispensing prescriptions. This finding alone does not indicate that the current pharmacy reimbursement rates are inadequate since both dispensing and ingredient reimbursement rates should be considered in tandem.[58]

A Kentucky report noted that other third party payers used ingredient cost payments to make up for low dispensing fees.

> Dispensing fees paid by most third party payers are set at levels well below the dispensing cost of most pharmacies. Margins are still realized on third party prescriptions, however, due to the level of ingredient reimbursement.[59]

48. These studies reported to state Medicaid agencies that dispensing fees were often inadequate to cover the costs of filing prescriptions. These reports also indicate that attempts to lower ingredient cost reimbursement by increasing the discount from AWP needed to be in the context of the resulting adequacy of the overall reimbursement.

49. There is substantial testimony in this matter from many state Medicaid officials that they were aware that their dispensing fees were inadequate to compensate pharmacists for filling prescriptions.[60] Officials testified that attempts to reduce

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[57] "A Survey of Acquisition Costs of Pharmaceuticals in the State of California," Myers and Stauffer, June 2002 at 4-5.
[58] "A Study of Medi-Cal Pharmacy Reimbursement," Myers and Stauffer, June, 2002 at 6.
[59] "A Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the Commonwealth of Kentucky, Myers and Stauffer, 2000 at 35.
[60] State officials testifying about the inadequacy of dispensing fees include Sullivan Deposition, Director of Pharmacy Services, TennCare, supra. note 51; Gorospe Deposition California Department of Human Services, supra. note 51; Wiberg Deposition Minnesota Department of Human Services, supra. note 51; Dubberly Deposition, Georgia Department of Community Health, supra. note 51; Ridout Deposition, North Carolina

reimbursements substantially would require increases in dispensing fees to compensate pharmacists. Cody Wiberg of the Minnesota Department of Human Services testified,

> ...you have to understand that there's two sides of the equation, that the dispensing fees are kept artificially low. That if you just reduce the ingredient reimbursement to actual acquisition cost, and don't do anything with the dispensing fee, there's at least the possibility that you're going to have access problems for patients, because pharmacies at that point might drop out of the system.
>
> [...]
>
> But if we move towards more transparency and we get closer to reimbursing on the ingredient side at what providers actually pay, then we have to look at the dispensing fee side in the case of pharmacies, because we've always kept that below what we think the true cost of dispensing is to make up for the fact that there is some money being made on the ingredient side. So to the extent, again, that you start paying people a dispensing fee or a total reimbursement that does not even get back the cost of the drugs, plus the cost of labor and the computer systems and the lights and all that, you could have providers...start dropping out of Medicaid.[61]

50. Jerry Dubberly of Georgia testified that the fact dispensing fees were kept low because ingredient costs were high was not only a common practice of the states he had contact with, but also that this practice was well known to the Federal agencies, HCFA or later, CMS.[62]

51. Officials from other states testified that their payments were intentionally set to allow for a profit to be paid to pharmacies. For example, Idaho's Medicaid statute mandates that pharmacy payments be based on the reasonable costs of filling

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Department of Health and Human Services, supra. note 51; Parker Deposition, Illinois Department of Healthcare and Human Services, supra. note 51; Terrebonne Deposition, Louisiana Department of Health and Hospitals, supra. note 51; Danemark Deposition, Delaware Division of Medicaid and Medical Assistance, supra. note 51; Vaccaro Deposition, New Jersey Department of Human Services, supra. note 51; and Wells Deposition, Florida State Medicaid, supra. note 51.

[61] Wiberg Deposition, supra. note 51 at 170-172.

[62] Dubberly Deposition, supra. note 51 at 384-386.

prescriptions, and must also include a profit for pharmacies.[63] Other states including Illinois[64], Oklahoma[65], and Tennessee[66] also sought to set payments so as to provide a profit to pharmacies.[67]

52. In his analysis, Dr. Duggan assumes that nothing in the Medicaid reimbursement changes but the ingredient cost reimbursement. Despite overwhelming evidence to the contrary, he assumes that even if ingredient cost reimbursements were based on his estimate of average acquisition cost, pharmacies would continue to participate in the Medicaid programs, even if the extant dispensing fees are inadequate to cover costs.

53. This assumption does not conform to reality. As an economist, it is clear to me that if the overall reimbursement (ingredient cost plus dispensing fee) does not cover the costs of filling prescriptions, these pharmacies will refuse to fill such prescriptions. Another Relator expert acknowledges this basic economic point. Dr. Stephen Schondelmeyer, in his recent report on proposed reductions in Medi-Cal pharmacy reimbursements in California writes,

> If the payment method sets the prescription payment amount below the actual costs for either drug product cost, cost of dispensing and related additional costs, or both, then problems with Medicare [sic] beneficiary access to pharmacy services will occur.
>
> ...Any reasonable pharmacy...would be unwilling to provide prescriptions when the total payment falls short of the total actual drug product costs and the costs of dispensing and other costs.[68]

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[63] Idaho Administrative Code, Agency 16.03.09.817.
[64] Parker Deposition at 137.
[65] Deposition of Nancy Nesser, Oklahoma Health Care Authority, December 12, 2008 at 60.
[66] Sullivan Deposition at 161.
[67] See, e.g., Danemark Depostion at 179:7-181:15; Parker Deposition at 137:13-21; Terrbonne Deposition at 216:5-217:4; Sullivan Deposition at 59:17-61:14, 62:13-63:3, 240:20-241:8; Wiberg Deposition at 67:15-69:21, 72:12-18, 183:17-186:12.

54. Dr. Schondelmeyer quantifies his estimate of the number of pharmacies serving Medicaid that would close if the new FULs under the Deficit Reduction Act of 2005 ("DRA") were to be enacted,

> Reduction in payments will result in substantial loss, even closures, for a number of pharmacies. In total, the loss of 20% of all retail pharmacies would not be unexpected from payment cuts of the magnitude that will result from the final rule. If a similar proportion of all types of retail pharmacies is affected, the retail pharmacy market may see the loss of 10,000 to 12,000 pharmacies...over the next few years.[69]

55. Dr. Schondelmeyer recognizes what Dr. Duggan fails to grasp: the total payment for the prescription, regardless of what portion is ingredient cost and what portion is dispensing fee, must cover the pharmacy's costs, otherwise they will not participate in Medicaid.

56. This threat to patient access was realized by Walgreens' recent decision to withdraw almost half of its pharmacies from the State of Washington Medicaid system.[70] Washington state enacted significant reductions in Medicaid drug reimbursements as of April 1, and the inadequacy of these reimbursements was the reason for the company's decision. This decision by one of the nation's leading drug store chains indicates that the threat to patient access resulting from inadequate drug reimbursements is not merely a hypothetical possibility.

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[68] Stephen Schondelmeyer, "Impact of the 10 Percent Fee-for-Service Payment Reductions on Medi-Cal Beneficiaries and Pharmacies," June 3, 2008 at ii.

[69] *National Assoc. of Chain Drug Stores v. United States Department of Health and Human Services*, Case No. 07-02017, Expert Report of Steven W. Schondelmeyer, Pharm.D., PH.D., November 15, 2007.

[70] "Walgreens to Stop Filling Medicaid Prescriptions at Nearly Half of Its Pharmacies in the State of Washington as of May 1," Online Wall Street Journal accessed at http://online.wsj.com/article/PR-CO-20090330-942688.html.

57. Dr. Duggan ignores copious evidence that existing dispensing fees do not cover the costs of storing, measuring and dispensing the drugs at issue in this matter. Dr. Duggan assumes that state Medicaid agencies can dramatically lower ingredient cost reimbursement to his version of average acquisition cost, and keep dispensing fees at their low, unremunerative levels. He assumes such drastic reductions in overall reimbursements would have no effect at all on pharmacy viability or continued participation in the Medicaid program.

58. Dr. Duggan sought to dismiss such concerns by claiming in deposition that the NDCs in this matter constitute only 43 out of over 25,000 NDCs, and that states would not alter their dispensing fee structure for such a small number of NDCs.[71] In my opinion, this argument directly contradicts the Relator's own representations of the scope of the alleged wrongful behavior at issue as well as Dr. Duggan's own experience in other similar matters in which he has testified. In a presentation to Federal officials in 1995, Ven-a-Care claimed the existence of a industrywide fraud resulting from manufacturers' alleged wrongful reporting of inflated prices. To claim now that the fraud involves only the 43 NDCs in this litigation contradicts the Relator's earlier position.

59. While the current matter involves only 43 NDCs, Dr. Duggan himself has served as an expert in similar cases where he has proposed identical changes in reporting and reimbursement for hundreds of other NDCs.[72] To claim that changes of the magnitude he proposes here would apply to only these 43 NDCs in the but-for world ignores both his own experience and the reality of numerous similar matters proceeding in State and Federal courts around the country.

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[71] Duggan Ery Deposition at 160.
[72] Id. at 162-163.

60. In light of the Relator's own presentation, as well as the dozens of similar actions proceeding in state and federal courts around the country with similar allegations, it is clear that the result of this litigation would in fact be a national, systemwide change in how prices are reported and reimbursements are calculated.

3. There is No Evidence of Any State Medicaid Program Adopting a Reimbursement Method Resembling the Method Assumed By Dr. Duggan

61. For all of the reports, testimony and other facts that Dr. Duggan ignores in constructing his version of the but-for world, the best test is to examine whether any state, in the decades since the alleged problems with the current reimbursement system were widely reported, has adopted a reimbursement system that resembles the system proposed by Dr. Duggan. If Dr. Duggan's proposed system were realistic, then we would expect the recent reimbursement changes enacted by the U.S. Congress to conform closely to what Dr. Duggan has proposed. While states and the federal government have modified reimbursement methods over the years, and major changes were enacted by Congress in 2005, Dr. Duggan has presented no evidence and no example, up to the present day, of a single state replacing the reimbursement system at issue here with one resembling his. Where states have lowered ingredient cost reimbursements and held dispensing fees constant, none have reduced ingredient cost reimbursements to an average acquisition cost calculated similarly to that of Dr. Duggan. In states that have substantially reduced ingredient cost reimbursements, such reductions have been accompanied by increases in dispensing fees.[73]

[73] For example, California lowered ingredient cost reimbursements from AWP - 10% in 2000 to AWP – 17% in 2004. However, dispensing fees were increased from $4.05 in 2000 to $7.25 in 2004.

62. In fact, while it is clear from the record that for many years public reports have shown that AWP is not the same as acquisition cost, the reimbursement system at issue in this litigation continues to be used widely. To this day, states continue to use, and CMS continues to approve State Implementation Plans using the scaled AWP methodology.[74] Attempts to change the reimbursement method have been met with political resistance and legal actions by physician and pharmacy associations. In some states, injunctions have been granted blocking proposed changes that were more modest than the changes proposed by Dr. Duggan.[75]

63. At the Federal level, HCFA revised the Medicaid manual in 1989 to require states' EACs to include a "significant discount" from AWP. One year later, Congress imposed a moratorium on state changes to pharmacy reimbursement policies lasting from 1990 until December 31, 1994. Dr. Duggan ignores this moratorium in his damage calculations.

64. It is instructive to compare Dr. Duggan's but-for world with the changes to the reimbursement method instituted by the Federal government. Congress enacted these changes in 2005 following extensive public discussion of the alleged shortcomings of the reimbursement system at issue here. If Dr. Duggan's vision of the but-for world is

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[74] See note 22 supra.

[75] Independent Living Center of Southern California, Inc. et al. v. Sandra Shewry, Director of Department Health Care Services, State of California, n. 08-56061, July 11, 2008; Arkansas Pharmacist Association v. Patricia Harris, Secretary of United States Department of Health and Human Services, n. 79-1592, February 12, 1980; Florida Pharmacy Association v. Douglas M. Cook 4:97cv322-r September 3, 1998; American Society of Consultant Pharmacists v. Ann Palta, Director of Illinois Department of Public Aid and The Illinois Department of Public Aid, case no. 00c7821, February 27, 2001; Pennsylvania Pharmaceutical Association v. Department of Public Welfare of the Commonwealth of Pennsylvania, case no. 80-1790, July 9, 1982.

correct, we should expect it to closely resemble the new methods enacted by Congress. It does not.

65. In 2005, Congress reformed the Medicaid reimbursement system as part of the DRA. Congress established a new FUL at 250% of the Average Manufacturer's Price (AMP) of the lowest cost therapeutically equivalent drug.[76] Generally, pharmacies will be reimbursed at the lesser of this FUL, a state MAC, if any; EAC, or the pharmacist's usual and customary charge (U&C). Pharmacies also receive a dispensing fee for FUL, EAC or MAC reimbursements. As part of the implementation of this new FUL, states were directed to review the accompanying dispensing fees to assure their adequacy,

> [S]tates should reexamine and reevaluate the reasonableness of the dispensing fee paid as part of the pharmacy claim. If States adjust their payment methodologies to reflect the ingredient cost of the prescription drug, we suggest that they also reevaluate their dispensing fees to ensure that these fees are reasonable.[77]

66. The differences between the actual system enacted by Congress and Dr. Duggan's purported but-for reimbursement system are significant. Dr. Duggan calculates his version of average acquisition cost, which is different than the Federal AMP. He then adds 25 percent to this amount, to arrive at his but-for version of AWP. He assumes that a 25 percent markup is adequate to cover provider profit margin and any dispensing, and delivery costs not covered by the dispensing fee. Congress, in reality, enacted a markup of 250 percent, ten times that proposed by Dr. Duggan. Second, Dr. Duggan's but-for reimbursement system does not allow dispensing fees to be adjusted to compensate

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[76] U.S. DHHS, Centers for Medicare and Medicaid Services, "Implementation of the Deficit Reduction Act (DRA) of 2005" Medicaid Drug Rebate Program, release No. 144, December 15, 2006 at 1. Accessed at http://www.cms.hhs.gov/DeficitReductionAct/Downloads/rel144.pdf.

[77] Id. at 2.

pharmacies for their actual costs of storing, measuring and delivering the drugs. Congress, again contrary to Dr. Duggan's assumption, expressly directed states to review their dispensing fees in light of the new FUL regulations to ensure their adequacy.

67. Dr. Duggan has assumed a but-for world for Medicaid pharmaceutical reimbursements far lower than what Congress actually enacted. This assumption has caused Dr. Duggan's calculation of alleged damages to be grossly inflated compared to what they would be if he had used as a but-for world the reimbursement calculation for Medicaid actually enacted by the Congress. Exhibit 5 shows for the top three NDCs, ranked by Dr. Duggan's difference calculation, the difference between Dr. Duggan's but-for AWP and the new government FUL from the DRA. For drugs like the ones at issue here, Medicaid would pay substantially more under the Congressionally mandated DRA FULs than it would pay under Dr. Duggan's proposed reimbursement system. In addition, states were directed to review the adequacy of their dispensing fees in light of any reductions in ingredient costs, which would further increase government payments under the DRA above the levels proposed by Dr. Duggan.

68. I note that this new FUL calculation, even with its 250 percent markup over AMP, has yet to be enacted. The National Association of Chain Drug Stores filed suit to block implementation of this change, arguing that the FUL calculation, despite being at least ten times higher than that envisioned by Dr. Duggan, remains inadequate to compensate pharmacies for their costs.[78]

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[78] *National Association of Chain Drug Stores et al., v. United States Department of Human Services et al.*, Case: 1:07-cv-02017, November 7, 2007.

4. Dr. Duggan's Damage Calculations Are Unscientific And Highly Speculative

70. Dr. Duggan's selects fifteen states out of fifty. For these fifteen states, he calculates an assumed but-for AWP equal to his estimate of average acquisition cost plus 25 percent. This but-for AWP is then scaled by whatever percentage discount was used in these states at a particular time to calculate a but-for reimbursement. He calculates damages by taking the difference between his calculation of the actual reimbursement paid by that state and his assumed but-for reimbursement. He then uses the difference between the two reimbursements for his fifteen states to extrapolate what he claims the damage would be in the other 34 states he analyzes. Within his fifteen exemplar states, he extrapolates damages for periods for which he does not have data.

71. First, Dr. Duggan introduces error into his estimates by extrapolating unnecessarily. CMS, the relevant government agency in this matter, should have access to all of the claims data for all of the state Medicaid programs. Dr. Duggan had the ability to directly conduct his alleged damage calculation using actual data from each of the state Medicaid programs. He chose instead to use actual claims data from only fifteen states, some with incomplete data across the relevant time period, and then to extrapolate damages to the other 34 states. By extrapolating in this way, he makes the baseless and untested assumption that the reimbursement systems and resulting reimbursements are the same between his exemplar states and the other 34. He provides no factual basis for such an assumption. He provides no statistical tests of the accuracy of his extrapolations. Dr. Duggan's use of out of sample extrapolation, instead of analyzing actual claims data, introduces needless error and uncertainty into his damage estimates.

72. Second, his fifteen "exemplar" states are chosen in an ad hoc and unscientific manner. This shortcoming further reduces confidence in his extrapolations, as the states from which he is extrapolating are not a random sample of the population. Dr. Duggan claims that he chose fifteen states accounting for over 70 percent of total reimbursements for these drugs.[79] His selection of these exemplar states is not random, and Dr. Duggan presents no evidence that it is.

73. Third, Dr. Duggan's extrapolations are simply mechanical exercises, paying no attention at all to the actual reimbursement system in any particular state. Dr. Duggan only manipulates the numbers in the data, paying scant attention to the circumstances of individual states and of individual claims. This mechanical methodology does not check the accuracy of the transaction entries, and does not reveal the basis of reimbursement. His method does not indicate whether any particular reimbursement was in fact based on AWP as opposed to some other non-AWP-based methodology, or whether his calculation of damages in fact made sense for any particular state. Without such inquiries, Dr. Duggan cannot even tell whether any particular transaction was actually affected by the alleged AWP manipulation, that is, whether Abbott should even be liable on a particular claim under the Relator's theory.

74. Dr. Duggan also makes no attempt to assess the information available or to address these issues in particular states to determine whether Medicaid transactions were in fact affected by the alleged AWP manipulation, or inconsistent with state policy. Evidence in the record indicates that officials in many states were quite knowledgeable about the facts of drug pricing, and were actively forming reimbursement policies in light

[79] Duggan Ery Report at 88.

of that knowledge. Dr. Duggan ignores the realities of state reimbursement policies, and assumes without basis that all states sought to set reimbursement equal to his calculation of acquisition cost, regardless of the consequences to provider solvency and patient access.

75. To contain drug spending, some states adopted Maximum Allowable Cost (MAC) rules for a wide range of multisource drugs, including erythromycin. MAC prices are generally the result of negotiation between the state Medicaid agency and pharmacies. Given the goals of the MAC program, MAC prices are a good indicator of the lowest reimbursement mutually acceptable to pharmacies and the state. Furthermore, MAC prices reflect state policy, and embody the state Medicaid agencies' balancing of the dual, but conflicting, mandates of cost containment and patient access.

76. Other states did not negotiate directly with pharmacies to determine MAC prices, but rather simply adopted the MAC price list paid by a third party payer operating in the state. That a third party payer was conducting negotiations does not change the conclusion that Dr. Duggan should not have considered such transactions to be fraudulent. Third-party payers face exactly the same problem as Medicaid agencies, that is, to contain drug spending while paying reimbursements high enough to maintain an adequate network of pharmacies to serve their insureds. That some states would economize on negotiation by adopting MAC prices negotiated by a private sector insurer with the same basic goals does not alter the conclusion that such MACs were the embodiment of a considered state policy, rather than a fraudulent reimbursement as Dr. Duggan apparently believes.

77. Dr. Duggan's methodology ignores all of this relevant history. He labels these negotiated MAC prices and federally mandated FUL prices as being too high and fraudulent, and assesses alleged damages each time a MAC or FUL price exceeds his but-for price. The fact that the state mandated MAC and/or the federal FUL price lies above his assumed but for price is taken as an indication of fraud, rather than as an indication of government agencies trying to control costs while assuring adequate access to their constituents.

78. Dr. Duggan takes great pains to claim that his alleged damage estimates are conservative—that is, favor Abbott—at every juncture in his analysis. In my opinion, it is not conservative to introduce error into one's estimates by extrapolating where one can calculate alleged damages directly. It is not conservative to base one's extrapolations on an unscientific, nonrandom and unrepresentative sample of the states, assuming away differences between his exemplar states and the other 34 states. It is not conservative to ignore the realities of state reimbursement policies, and instead base one's estimates on a but-for world that has not been adopted by a single state in the eight years since the filing of this matter. It is not conservative to ignore well-considered state and federal policies designed to contain costs and ensure access, and to label as fraudulent and wrongful drug reimbursements made under such policies. In my opinion, such obvious omission of important institutional details renders Dr. Duggan's alleged damage estimates inaccurate and unreliable.

VI. Concluding Comments

79. For all of the foregoing reasons, it is my opinion that Dr. Duggan's estimates are flawed, inaccurate and unreliable.

I reserve my right to supplement my opinions at trial or as new information warrants.

Dated: May 8, 2009

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WORK IN PROGRESS

"Reasons for the Shrinking Effective Patent Life of New Pharmaceuticals," (with A. Taylor, '04).

COURSES TAUGHT:

Industrial Organization and Antitrust Policy
Law and Economics
Business and Government
Labor Economics
Health Economics
The Economics of Women, Men, and Work
Environmental and Natural Resource Economics
Property, Liberty, and Law
Environmental Issues in Economic Development
Earth Under Siege: Global Warming and Atmospheric Change
Sustaining the Masses: Economic Development and Environmental Protection in the People's Republic of China
Principles of Macroeconomics
Principles of Microeconomics
Intermediate Microeconomic Theory

PRESENTATIONS: "The Economic Status of China's Ethnic Minorities," (with M. Maurer-Fazio), Western Economics Association Pacific Rim Conference, Hong Kong SAR, China, January, 2005.

"'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare," (with M. Moore and E. Snyder), Applied Microeconomics and Economic and Legal Organization, Graduate School of Business, University of Chicago, October, 2002.

"'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare," (with M. Moore and E. Snyder), Annual Meeting of the Pharmaceutical Economics and Policy Council, Washington, DC, January 2002.

"The Gender Wage Gap in Urban China: The Effects of Institutional Change," (with M. Maurer-Fazio), Allied Social Sciences Association, Boston, MA January, 2000.

"The Effect of Job Mobility on Academic Salaries," (with D. Barbezat), Western Economics Association Meetings, San Diego, CA July, 1999.

"The Economics of the 'Loser-Pays" Rule," Edward T. Gignoux Inn of Court, Portland, Maine, February 12, 1997.

Keynote Address, Matriculation Dinner for the Class of 1999, Bates College, September 5, 1995.

Breckenridge Lecture,"Is the English Rule Really Cheaper?" Colby College, April 26, 1995.

"Can the English Rule Cure the Ills of Medical Malpractice?" presented to the Androscoggin County Medical Society, March 16, 1995.

"What Blue Cross Knows Can Hurt You: Ethical Dilemmas in Private Medical Insurance," TGIF Lecture, Muskie Archives, March 3, 1995.

"Female Academics: Mobility and the Returns to Seniority," Annual Meetings of the Southern Economics Association, Orlando, FL November 20, 1994.

Breckenridge Lecture, "Economics of the English Rule," Colby College, April 20, 1994.

"Health Care Reform and Medical Malpractice: Smoke or Fire?" TGIF Lecture, Muskie Archives, March 4, 1994.

"Litigation Under the English and American Rules: Theory and Evidence," Annual Meetings of The American Economics Association, Boston, Massachusetts, January 5, 1994.

"Marketable Permits for Chlorofluorocarbon Regulation," Colby College, October, 1993.

"Litigation Under the English and American Rules: Theory and Evidence," Research Seminar in Law and Economics, Harvard Law School, April 7, 1993.

"Litigation Under the English and American Rules: Theory and Evidence," Annual Meeting of the American Law and Economics Association, Yale University, May 1, 1992.

"NIMBY and the Location of Drug Treatment Facilities," National Institute on Drug Abuse, July, 1991.

American Bar Association, "Litigation, Justice, and the Public Good," San Diego, CA April 25-27, 1991.

"Contingent Fees, Litigation, and the Quantity of Litigation," Annual Meeting of the Law and Society Association, May 31, 1990, Berkeley, CA

"The English Rule for Allocating Legal Costs: Evidence Confronts Theory," Annual Meeting of the Law and Society Association, Madison, WI, June 1, 1989.

"Controlling for Sample Selection in the Analysis of Closed Claim Data," Annual Meetings of the Western Economics Association, Vancouver, BC, Canada, July, 1988.

"Medical Malpractice Reforms and the Resolution of Claims," Annual Meetings of the Eastern Economics Association, Arlington, VA March, 1987.

"Is the Sample of Litigated Claims Random? Preliminary Results of a Trivariate Probit Estimator," Annual Meetings of the Eastern Economics Association, Baltimore, MD, March, 1986.

PROFESSIONAL SERVICE

Referee for: *Journal of Law and Economics, International Review of Law and Economics, Economic Inquiry, Journal of Risk and Insurance, Journal of Law, Economics, and Organization, Journal of Policy Analysis and Management, Behavioral Science and the Law, Social Sciences Quarterly.*

Reviewer for the National Science Foundation.

GRANTS AND AWARDS:

"Inspirational Hall of Fame," Alfond Youth Center, Waterville, Maine, May, 2005.

Paganucci Award for Outstanding Community Service, Alfond Youth Center, Waterville, Maine, 2004.

Joint Student-Faculty Research Grant (with D. Barsky, '03), Freeman Foundation Asian Studies Grant Program, Bates College, 2002.

Curriculum Development Grant (with M. Maurer-Fazio and S. Yang), Freeman Foundation Asian Studies Grant Program, Bates College, 2002.

Mellon Summer Research Apprenticeship, Bates College, 2000.

Mellon Summer Research Apprenticeship, Bates College, 1998

The President's Fund for Faculty and Curricular Development, Bates College, 1997-1998.

Curricular Development Grant, Otis Fund, Bates College, 1997.

Mellon Summer Research Apprenticeship, Bates College, 1996.

Kroepsch Award for Excellence in Teaching, 1994-1995, Bates College.

Amherst College Research Award (1991-1992) to examine the effect of no-fault medical malpractice insurance on the size of awards, the number of claims, and the number of medical injuries.

Post-Doctoral Research Fellow in the Economics of Mental Health, Brandeis University, Florence Heller School for Advanced Studies in Social Welfare, 1990-1991.

Research grant from The Robert Wood Johnson Foundation Medical Malpractice Program (1987-1988) to examine the long-term effects of medical malpractice reform legislation on the size, frequency, and disposition of medical malpractice claims.

Miner D. Crary Fellow, Amherst College, 1988-1989.

NON-ACADEMIC POSITIONS:

LITIGATION CONSULTANT, 1990-
Economic expert for antitrust, regulation, and discrimination litigation. Retained on several cases involving the pharmaceutical industry, the prescription benefit manager industry, the environmental control industry, the synthetic rubber industry, nutritional supplement industry, the hospital industry, the automobile insurance industry, the sardine market, retail automobile sales, the retail gasoline market, school photography, musical instruments, airline transportation, and sex discrimination.

BRANDEIS INSTITUTE FOR HEALTH POLICY, Waltham, MA
1992-1993
Co-Author of a report on the residential housing market in the San Francisco-Oakland Bay Area, and the effect on property values resulting from locating residential drug treatment facilities in that market. Co-Author of a study of the effects on Medicaid expenditures of extending coverage for outpatient and residential drug treatment to pregnant drug users.

THE RAND CORPORATION, Santa Monica, CA 1985-1986.
Consultant on a study of the European chlorofluorocarbon industry for the U.S. Environmental Protection Agency. Examined the effect of proposed regulations on competition within the European chemical industry.

ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, Paris, France, 1982-1983
Author of a report to the Environment Directorate on the socioeconomic implications of chlorofluorocarbon emissions and their control in the OECD nations. Report assessed progress in controlling emissions and quantifies the potential economic effects of further emissions reductions.

SRI INTERNATIONAL, Menlo Park, CA 1981.
Consultant to the Regulatory Analysis and Management Program. Project included construction of a programming model to assist petroleum refineries in finding the least cost method of reducing emissions of volatile organic chemicals. Author of a manual on the use of information disclosure in regulatory reform for the President's Regulatory Council.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, DC, 1978-1980.
Economist in the Office of Pesticides and Toxic Substances. Authored several reports on the effects of regulating toxic chemicals through the use of marketable rights. Responsible for economic analyses of proposed regulations to limit uses of chlorofluorocarbons and asbestos.

EXHIBIT 2

James W. Hughes

Experience as Testifying Expert

Patricia Griffiths v. Eastern Maine Medical Center, U.S. District Court, ME, Civil Action 2:2008-CV-00220

Putney, Inc. v. Pfizer Inc. and MWI Veterinary Supply, U.S. District Court, ME, Civil Docket No. 2:07-cv-00108-DBH

In Re Pharmaceutical Industry Average Wholesale Price Litigation, In the matters of: *State of Nevada v. American Home Prods. Corp., et al.*, 02-CV-12086-PBS; **and** *State of Montana v. Abbott Labs., Inc., et al.*, 02-CV-12084-PBS, **MDL NO. 1456, Master File No. 01-CV-12257-PBS**

Axiom Plastics v. E.I. DuPont Canada Company, Ontario (Canada) Sup.Ct. Court File No. 05-CV-302358 CP

State of Connecticut v. Aventis Pharmaceuticals, Docket X07 CV03-0083299 S (CLD)

Brady Enterprises, et al. v. Medco Health Solutions, et al., U.S. District Court, E.D. Penn., Civ. No. 03-4730

In Re NBR Antitrust Litigation, U.S. District Court, W.D. Pa., Civil Action No. 03-1898

EXHIBIT 3

U.S.A., ex rel., Ven-A-Care v. Abbott (ERY Litigation)

INDEX OF DOCUMENTS FOR JAMES W. HUGHES

TAB	DESCRIPTION	DATE
1.	Aventis Pharmaceutical's Disclosure of Expert Witness, James Hughes (re: State of Connecticut v. Aventis)	05/25/06
2.	Declaration of James W. Hughes, Ph.D. Submitted on Behalf of Aventis Pharmaceuticals Inc.	02/08/07
3.	James Hughes Signed Retention Letter and Signed Certification re: Protective Order	
4.	Abbott Laboratories, Inc.'s Motion to Dismiss or partially dismiss the relators' complaint. • Abbott's Memo in Support of Motion to Dismiss • Ex-A-1995 Original Complaint • Ex-B-1997 1st Amended Florida Qui-Tam-Complaint • Ex-C-2nd Amended Florida-Qui-Tam-Complaint • Ex-D-3rd Amended Florida Qui-Tam-Complaint • Ex-E-Redacted Original Complaint • Ex-F-Redacted 1st Amended Complaint • Ex-G-Redacted 2nd Amended Complaint • Ex-H-2002-4th Amended Florida Complaint • Ex-I-Redacted 3rd Amended-Complaint • Ex-J-Notice to Intervene • Ex-K-2006 Govt. Complaint in Intervention • Ex-L-VAC Motion to Amend Complaint • Ex-M-Order Granting Leave to Amend • Ex-N-Transfer Order - Florida to District of Massachusetts • Ex-O-8/30/07 COMPLAINT against Abbott filed by Ven-A-Care-of-the-Florida-Keys Inc. • Ex-P-Motion to Transfer Case to MDL No.-1456 • Ex-Q-Chronology of Events	10/30/07
5.	Letter to James Hughes enclosing one CD containing several depositions transcripts/exhibits for review:	05/13/08

<table>
<tr><th>TAB</th><th>DESCRIPTION</th><th>DATE</th></tr>
<tr><td></td><td>
<table>
<tr><td>Amy Bassano</td><td>Amy Sernyak</td><td>Bruce Vladeck</td></tr>
<tr><td>Charles Booth</td><td>Claire Hardwick</td><td>Curtis Collison</td></tr>
<tr><td>Cynthia Hansford</td><td>David Tawes</td><td>David Timus</td></tr>
<tr><td>Dennis Smith</td><td>Don Thompson</td><td>Elizabeth Richter</td></tr>
<tr><td>Glenda Bailey</td><td>John Hoover</td><td>John Warren</td></tr>
<tr><td>Joseph Bryant</td><td>Joyce Somsak</td><td>Julie Boughn</td></tr>
<tr><td>Kimberly Howell</td><td>Larry Reed</td><td>Linda Ragone</td></tr>
<tr><td>Lisa Parker</td><td>Marianne Bowen</td><td>Nancy-Ann DeParle</td></tr>
<tr><td>Nancy Molyneaux</td><td>Pearl Brown</td><td>Richard Morris</td></tr>
<tr><td>Robert Berenson</td><td>Robert Nieman</td><td>Robert Vito</td></tr>
<tr><td>Sue Gaston</td><td>Thomas Gustafson</td><td>Tom Scully</td></tr>
<tr><td>Victoria Robey</td><td></td><td></td></tr>
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<tr><td>6.</td><td>Letter to James Hughes enclosing two CDs containing several depositions transcripts/exhibits for review:
<table>
<tr><td>Brenda McCormick</td><td>Cody Wiberg</td><td>Deidre Duzor</td></tr>
<tr><td>Harry Sullivan</td><td>James Kenyon</td><td>Jerry Wells</td></tr>
<tr><td>Jude Walsh</td><td>Keven Gorospe</td><td>Mary J. Terrebonne</td></tr>
<tr><td>Maryanne Paccione</td><td>Michael Sharp</td><td>Sandra Kramer</td></tr>
<tr><td>John Lockwood</td><td>Luis Cobo</td><td>T. Mark Jones</td></tr>
<tr><td>Zachary Bentley</td><td></td><td></td></tr>
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</td><td>05/14/08</td></tr>
<tr><td>7.</td><td>Letter to J. Hughes from C. Geisler enclosing a CD containing the deposition transcripts and exhibits of Kathleen Buto.</td><td>06/04/08</td></tr>
<tr><td>8.</td><td>Letter to J. Hughes from C. Geisler enclosing a CD containing and binders containing the deposition transcripts of the following:
<table>
<tr><td>Danny Cottrell</td><td>George Hiller</td><td>Charles Kenneth Sanders, Jr.</td></tr>
<tr><td>Tim Sawyers</td><td>Michael Vinson</td><td>Debra Bahr</td></tr>
<tr><td>T. Allan Hansen</td><td>Kenneth Troy Koch</td><td>Walton Louis Moore, M.D.</td></tr>
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</td><td>06/12/08</td></tr>
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TAB	DESCRIPTION	DATE
	Mike Robinson; Charles Duarte; Aileen Hiramatsu Lucinda Brandt; Gary P. Gilmore; Diane Jacobs Paul L. Jeffrey, Pharm. D.; Douglas A. Lapp; Arnold H. Shapiro Vic J. Vangel; George Oestreich; Susan McCann Theodore M. Collins; Christopher J. Decker R.Ph.; Gary A. Donaldson Kimberly A. Hodgkinson; Russell J. Jensen; Susan L. Sutter R.Ph. Nicole Y. Valentine	
9.	Letter to J. Hughes from C. Geisler enclosing two binders containing various OIG reports from 1995-2005. **Binder Title: OIG mid-1990 11-State Survey** **Contents:** DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services," May, 1996, A-06-95-00062, aka Abbott 325 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Public Health and Human Services," June 1996, A-06-95-00068, aka Abbott 327 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Florida Agency for Health Care Administration," August 1996, A-06-95-00065, aka Abbott 84 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the North Carolina Department of Human Resources," September 1996, A-06-95-00071 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Delaware Department of Health and Social Services," September 1996, A-06-95-00063 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the New Jersey Department of Human Services," December 1996, A-06-95-00070 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Nebraska Department of Social Services," December 1996, A-06-95-00069 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services,"	06/18/08

TAB	DESCRIPTION	DATE
	January 1997, A-06-95-00067 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the District of Columbia Department of Human Services," January 1997, A-06-95-00064 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Maryland Department of Health and Mental Hygiene," February 1997, A-06-95-00066 DHHS OIG "Medicaid Pharmacy—Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs," April 1997, A-06-96-00030 DHHS OIG "Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products," August 1997, A-06-97-00011 aka Abbott 158 **Binder Title: Follow Up OIG Work Comparing AWP with Acquisition Cost (1999-2005)** **Contents:** State of Utah, Department of Health, Division of Health Care Financing, "Medicaid Pharmacy—Acquisition Cost of Generic Prescription Drug Products," February, 1999 DHHS OIG "Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products," August, 2001, A-06-00-00023 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Washington Department of Social and Health Services," November, 2001 A-06-01-00006 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Colorado Department of Health Care Policy and Financing," November, 2001, A-06-01-00004 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Texas Health and Human Services Commission," November, 2001, A-06-01-00001 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Indiana Family and Social Services Administration," December, 2001, A-06-01-00008 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Wisconsin Department of Health and Family Services," March, 2002 A-06-01-00003 DHHS 010 "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Florida Agency for Health Care Administration," February, 2002, A-06-01-00002 DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Public Health and Human Services," February, 2002 A-06-01-00005	

TAB	DESCRIPTION	DATE
	DHHS OIG "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the West Virginia Department of Health and Human Resources," December, 2001 A-06-01-00007 DHHS OIG "Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products," March, 2002, A-06-01-00053 DHHS OIG "Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products," September, 2002, A-06-02-00041 DHHS OIG "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices," June, 2005 OE1-05-05-00240 DHHS OIG "Medicaid Drug Price Comparisons: Average Sales Price to Average Wholesale Price," June, 2005 OE1-03-05-00200 DHHS OIG "A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005," June, 2006 OE1-03-05-00430 DHHS OIG "States' Use of New Drug Pricing Data in the Medicaid Program," April, 2007 OE1-03-06-00490	
10.	Letter to J. Hughes from C. Geisler enclosing CDs with deposition transcripts and exhibits for the following: Jerry Wells — Edward Vaccaro Jerry Dubberly — Nancy Nesser James Parker — John Young Carl Shirley — Howard Tomlinson Mary J. Terrebonne — Ayuni Hautea-Wimpee Joseph Fine — Myra Davis Lisa Weeks — Colleen Jones Gary Cheloha — Leslie Milliken Lise Farrand — Roxanne Homar	01/08/09
11.	Letter to J. Hughes from C. Geisler enclosing CDs with deposition transcripts and exhibits for the following: David Campana — Edward J. Vaccaro Kevin Gorospe — Robert Stevens	01/13/09

TAB	DESCRIPTION	DATE
	Allen Chapman Cynthia Denemark Frank O'Connor Frank T. Tetkoski Anne Haase Brendan Joyce Margaret Clifford Benny Ridout Woo Pill Hwang Robert Reid Jesse Anderson Kathy Ketchum Paula Avarista Larry Iversen Ann Rugg	
12.	Letter to J. Hughes from C. Geisler enclosing CDs with deposition transcripts and exhibits for the following: Paul Chesser Suzette Bridges Benny Ridout Keith Hayashi	01/14/09
13.	Letter to J. Hughes from C. Geisler enclosing a CD containing deposition transcripts and exhibits for T. Allen Hansen of Myers and Stauffer w/ various Myers and Stauffer pharmacy reports.	02/12/09
14.	Letter to J. Hughes from C. Geisler enclosing a document bates labeled MD0003813-MD0003855.	04/22/09
15.	VAC/ERY Retention letter to J. Hughes dated 4/22/09 from E. Berlin.	04/22/09
16.	Electronic Orange Book, accessed online at www.fda.gov/cder/ob/docs/queryai.	
17.	David Besanko, David Dranove, and Mark Shanley, *The Economics of Strategy,* 2d ed., (New York, John Wiley & Sons, 2000).	
18.	Fiona Scott-Morton, "The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules," Rand Journal of Economics, v.28 n. 2, Summer, 1997, "The Interaction between a Most-Favored-Customer Clause and Price Dispersion: an Empirical Examination of the Medicaid Rebate Rules of 1990," Journal of Economics and Management Strategy, v.6 n. 1, Spring 1997.	
19.	Roger Blair and William Page, "Speculative Antitrust Damages," 70 Wash. L. Rev., April 1995.	
20.	U.S. Health and Human Services, Centers for Medicare and Medicaid, "Medicaid Prescription Reimbursement Information by State—Quarter Ending December, 2008," accessed online at http://www.cms.hhs.gov/Reimbursement/Downloads/MedicaidPrescriptionReimbursem	

TAB	DESCRIPTION	DATE
	entInformationbyStateDecember2008.pdf	
21.	U.S. Department of Health, Education and Welfare, "Task Force on Prescription Drugs: The Drug Makers and Drug Distributors," U.S. Government Printing Office, 1968.	
22.	U.S. DHEW, "Proposed Reimbursement of Drug Cost," 39 Fed. Reg. 230, 41,480, November 27, 1974.	
23.	HCFA Action Transmittal 77-113 (MMB) —Formula for Determining EAC for Drugs ¶28,714.	
24.	HCFA Action Transmittal, No. 84-12, September, 1984, "Medicaid—Limitation of Payment for Drugs" ¶34,157.	
25.	Federal Register, "Part 447: Payments for Services" 52 Fed. Reg. 147, 28557, July 31, 1987.	
26.	United States Senate, Special Committee on Aging, "Prescription Drug Prices: Are We Getting Our Money's Worth?" August, 1989.	
27.	U.S. House of Representatives, 102d Congress, Subcommittee on Health and the Environment, "Prescription Drug Rebate Program," Hearing, July 31, 1992.	
28.	President William Clinton, Radio Address 12/13/97, John T. Woolley and Gerhard Peters, *The American Presidency Project* [online]. Santa Barbara, CA: University of California (hosted), Gerhard Peters (database). Available from World Wide Web: http://www.presidency.ucsb.edu/ws/?pid=53703.	
29.	Idaho Administrative Code, 16.03.09.817.	
30.	Stephen Schondelmeyer, "Impact of the 10 Percent Fee-for-Service Payment Reductions on Medi-Cal Beneficiaries and Pharmacies," June 3, 2008.	
31.	*National Assoc. of Chain Drug Stores v. United States Department of Health and Human Services*, Case No. 07-02017, Expert Report of Steven W. Schondelmeyer, Pharm.D., PH.D., November 15, 2007.	
32.	"Walgreens to Stop Filling Medicaid Prescriptions at Nearly Half of Its Pharmacies in the State of Washington as of May 1," Online Wall Street Journal, accessed at http://online.wsj.com/article/PR-CO-20090330-942688.html.	
33.	U.S. DHHS, Centers for Medicare and Medicaid Services, "Implementation of the Deficit Reduction Act (DRA) of 2005" Medicaid Drug Rebate Program, release No. 144, December 15, 2006. Accessed at http://www.cms.hhs.gov/DeficitReductionAct/Downloads/rel144.pdf.	
34.	*National Association of Chain Drug Stores et al., v. United States Department of Human Services et al.*, Case: 1:07-cv-02017, November 7, 2007.	
35.	*Independent Living Center of Southern California, Inc. et al. v. Sandra Shewry, Director of Department Health Care Services, State of California*, n. 08-56061, July 11, 2008; *Arkansas Pharmacist Association v. Patricia Harris, Secretary of United States Department of Health and*	

TAB	DESCRIPTION	DATE
	Human Services, n. 79-1592, February 12, 1980; *Florida Pharmacy Association v. Douglas M. Cook* 4:97cv322-r September 3, 1998; *American Society of Consultant Pharmacists v. Ann Palta, Director of Illinois Department of Public Aid and The Illinois Department of Public Aid,* case no. 00c7821, February 27, 2001; *Pennsylvania Pharmaceutical Association v. Department of Public Welfare of the Commonwealth of Pennsylvania*, case no. 80-1790, July 9, 1982.	

EXHIBIT 4

Exhibit 4

00074632013 - Ery-tab 333 mg

Year	Quarter	A AMP	B Pharm Indirect Wt Average Price	(A - B) / B Pharm Indirect Average Price vs. AMP
1994	1	0.0976	0.1054	-7.46%
1994	2	0.0975	0.1058	-7.85%
1994	3	0.0950	0.0961	-1.21%
1994	4	0.0990	0.0972	1.87%
1995	1	0.0953	0.0973	-2.04%
1995	2	0.0874	0.0968	-9.77%
1995	3	0.0903	0.0961	-6.06%
1995	4	0.0882	0.0959	-8.09%
1996	1	0.0874	0.0954	-8.45%
1996	2	0.0835	0.0961	-13.08%
1996	3	0.0897	0.0951	-5.74%
1996	4	0.0901	0.0948	-4.99%
1997	1	0.0950	0.0949	0.13%
1997	2	0.0863	0.0948	-8.96%
1997	3	0.0954	0.1018	-6.22%
1997	4	0.0967	0.1019	-5.09%
1998	1	0.0951	0.1019	-6.61%
1998	2	0.0914	0.1016	-10.04%
1998	3	0.0942	0.1017	-7.37%
1998	4	0.0911	0.1022	-10.89%
1999	1	0.1001	0.1029	-2.72%
1999	2	0.0909	0.1019	-10.78%
1999	3	0.0986	0.1036	-4.84%
1999	4	0.1019	0.1036	-1.71%
2000	1	0.1011	0.1027	-1.61%
2000	2	0.0913	0.1020	-10.52%
2000	3	0.0963	0.1013	-4.89%
2000	4	0.0974	0.1010	-3.57%
2001	1	0.0851	0.1013	-16.04%
2001	2	0.0881	0.1025	-14.04%
2001	3	0.0966	0.1024	-5.67%
2001	4	0.0937	0.1022	-8.38%
2002	1	0.0857	0.1011	-15.21%
2002	2	0.0937	0.1010	-7.17%
2002	3	0.0929	0.1010	-8.10%
2002	4	0.0924	0.1010	-8.54%
2003	1	0.0849	0.1010	-16.02%
2003	2	0.0888	0.1011	-12.15%
2003	3	0.1815	0.1970	-7.85%
2003	4	0.1917	0.2013	-4.80%

00074631613 - Erythromycin Stearate 500 Mg Tab 100's

Year	Quarter	A AMP	B Pharm Indirect Wt Average Price	(A - B) / B Pharm Indirect Average Price vs. AMP
1994	1	0.1125	0.1165	-3.41%
1994	2	0.1131	0.1174	-3.66%
1994	3	0.1152	0.1101	4.58%
1994	4	0.1113	0.1104	0.85%
1995	1	0.1175	0.1105	6.25%
1995	2	0.1062	0.1103	-3.74%
1995	3	0.1092	0.1137	-3.98%
1995	4	0.1118	0.1138	-1.79%
1996	1	0.1065	0.1138	-6.42%
1996	2	0.1083	0.1139	-4.99%
1996	3	0.1110	0.1138	-2.40%
1996	4	0.1124	0.1140	-1.33%
1997	1	0.1124	0.1140	-1.42%
1997	2	0.1117	0.1139	-2.00%
1997	3	0.1185	0.1218	-2.64%
1997	4	0.1196	0.1218	-1.79%
1998	1	0.1245	0.1218	2.23%
1998	2	0.1100	0.1218	-9.71%
1998	3	0.1184	0.1219	-2.89%
1998	4	0.1168	0.1217	-4.05%
1999	1	0.1180	0.1220	-3.28%
1999	2	0.1160	0.1218	-4.77%
1999	3	0.1124	0.1237	-9.14%
1999	4	0.1214	0.1238	-2.01%
2000	1	0.1245	0.1234	0.92%
2000	2	0.1195	0.1227	-2.59%
2000	3	0.1214	0.1225	-0.90%
2000	4	0.1194	0.1224	-2.46%
2001	1	0.1085	0.1223	-11.28%
2001	2	0.1120	0.1223	-8.41%
2001	3	0.1157	0.1235	-6.33%
2001	4	0.1150	0.1237	-7.07%
2002	1	0.1102	0.1233	-10.66%
2002	2	0.1151	0.1234	-6.78%
2002	3	0.1220	0.1234	-1.09%
2002	4	0.1146	0.1231	-6.92%
2003	1	0.1076	0.1234	-12.75%
2003	2	0.1120	0.1233	-9.18%
2003	3	0.1241	0.1298	-4.35%
2003	4	0.1249	0.1302	-4.05%

00074632053 - Ery-tab 333 mg

Year	Quarter	A AMP	B Pharm Indirect Wt Average Price	(A - B) / B Pharm Indirect Average Price vs. AMP
1994	1	0.0976	0.0984	-0.91%
1994	2	0.0975	0.0996	-2.07%
1994	3	0.0950	0.0937	1.33%
1994	4	0.0990	0.0945	4.76%
1995	1	0.0953	0.0949	0.47%
1995	2	0.0874	0.0947	-7.74%
1995	3	0.0903	0.0945	-4.49%
1995	4	0.0882	0.0944	-6.56%
1996	1	0.0874	0.0942	-7.21%
1996	2	0.0835	0.0942	-11.36%
1996	3	0.0897	0.0938	-4.46%
1996	4	0.0901	0.0941	-4.27%
1997	1	0.0950	0.0943	0.79%
1997	2	0.0863	0.0945	-8.63%
1997	3	0.0954	0.1010	-5.53%
1997	4	0.0967	0.1010	-4.20%
1998	1	0.0951	0.1011	-5.91%
1998	2	0.0914	0.1007	-9.22%
1998	3	0.0942	0.1007	-6.46%
1998	4	0.0911	0.1004	-9.33%
1999	1	0.1001	0.1005	-0.38%
1999	2	0.0909	0.1002	-9.25%
1999	3	0.0986	0.1026	-3.92%
1999	4	0.1019	0.1021	-0.21%
2000	1	0.1011	0.1010	0.11%
2000	2	0.0913	0.1003	-8.98%
2000	3	0.0963	0.1003	-4.02%
2000	4	0.0974	0.0997	-2.30%
2001	1	0.0851	0.0992	-14.25%
2001	2	0.0881	0.0992	-11.11%
2001	3	0.0966	0.0994	-2.87%
2001	4	0.0937	0.0994	-5.79%
2002	1	0.0857	0.0986	-13.03%
2002	2	0.0937	0.0984	-4.74%
2002	3	0.0929	0.0985	-5.75%
2002	4	0.0924	0.0986	-6.33%
2003	1	0.0849	0.0986	-13.91%
2003	2	0.0888	0.0986	-9.90%
2003	3	0.1815	0.1857	-2.24%
2003	4	0.1917	0.1904	0.67%

EXHIBIT 5

Exhibit 5

00074632013 - Ery-tab 333 mg

Year	Quarter	A: AMP * 2.50 (MMA FUL)	B: Duggan "But For" AWP	(A - B) / B: MMA FUL vs. Duggan But For AWP
1994	1	0.2439	0.1318	85.03%
1994	2	0.2438	0.1323	84.28%
1994	3	0.2374	0.1202	97.52%
1994	4	0.2476	0.1215	103.77%
1995	1	0.2383	0.1216	95.95%
1995	2	0.2184	0.1210	80.48%
1995	3	0.2257	0.1201	87.89%
1995	4	0.2204	0.1199	83.84%
1996	1	0.2184	0.1193	83.09%
1996	2	0.2088	0.1201	73.83%
1996	3	0.2242	0.1189	88.52%
1996	4	0.2252	0.1185	90.00%
1997	1	0.2376	0.1186	100.32%
1997	2	0.2159	0.1185	82.15%
1997	3	0.2386	0.1272	87.58%
1997	4	0.2418	0.1274	89.80%
1998	1	0.2378	0.1273	86.82%
1998	2	0.2285	0.1270	79.90%
1998	3	0.2354	0.1271	85.21%
1998	4	0.2277	0.1277	78.27%
1999	1	0.2503	0.1286	94.60%
1999	2	0.2274	0.1274	78.45%
1999	3	0.2465	0.1295	90.31%
1999	4	0.2547	0.1295	96.64%
2000	1	0.2527	0.1284	96.83%
2000	2	0.2283	0.1275	79.02%
2000	3	0.2408	0.1266	90.17%
2000	4	0.2436	0.1263	92.85%
2001	1	0.2127	0.1267	67.88%
2001	2	0.2204	0.1282	71.88%
2001	3	0.2415	0.1280	88.65%
2001	4	0.2342	0.1278	83.24%
2002	1	0.2143	0.1264	69.54%
2002	2	0.2343	0.1262	85.68%
2002	3	0.2322	0.1263	83.81%
2002	4	0.2310	0.1263	82.90%
2003	1	0.2121	0.1263	67.95%
2003	2	0.2221	0.1264	75.71%
2003	3	0.4538	0.2462	84.32%
2003	4	0.4792	0.2516	90.44%

00074631613 - Erythromycin Stearate 500 Mg Tab 100's

Year	Quarter	A: AMP * 2.50 (MMA FUL)	B: Duggan "But For" AWP	(A - B) / B: MMA FUL vs. Duggan But For AWP
1994	1	0.2813	0.1456	93.20%
1994	2	0.2828	0.1468	92.66%
1994	3	0.2879	0.1377	109.10%
1994	4	0.2783	0.1380	101.65%
1995	1	0.2936	0.1382	112.46%
1995	2	0.2655	0.1379	92.51%
1995	3	0.2731	0.1422	92.02%
1995	4	0.2795	0.1423	96.42%
1996	1	0.2662	0.1422	87.20%
1996	2	0.2707	0.1424	90.06%
1996	3	0.2776	0.1422	95.22%
1996	4	0.2811	0.1424	97.40%
1997	1	0.2809	0.1425	97.11%
1997	2	0.2791	0.1424	96.01%
1997	3	0.2964	0.1522	94.71%
1997	4	0.2990	0.1522	96.42%
1998	1	0.3113	0.1523	104.40%
1998	2	0.2750	0.1523	80.55%
1998	3	0.2959	0.1523	94.27%
1998	4	0.2920	0.1521	91.95%
1999	1	0.2949	0.1524	93.50%
1999	2	0.2900	0.1523	90.43%
1999	3	0.2811	0.1547	81.69%
1999	4	0.3034	0.1548	95.98%
2000	1	0.3113	0.1542	101.86%
2000	2	0.2987	0.1533	94.85%
2000	3	0.3035	0.1531	98.25%
2000	4	0.2984	0.1530	95.03%
2001	1	0.2713	0.1529	77.45%
2001	2	0.2800	0.1528	83.23%
2001	3	0.2893	0.1544	87.35%
2001	4	0.2875	0.1547	85.84%
2002	1	0.2755	0.1542	78.65%
2002	2	0.2876	0.1543	86.41%
2002	3	0.3050	0.1542	97.80%
2002	4	0.2865	0.1539	86.14%
2003	1	0.2691	0.1542	74.50%
2003	2	0.2800	0.1541	81.67%
2003	3	0.3103	0.1622	91.32%
2003	4	0.3122	0.1627	91.90%

00074632053 - Ery-tab 333 mg

Year	Quarter	A: AMP * 2.50 (MMA FUL)	B: Duggan "But For" AWP	(A - B) / B: MMA FUL vs. Duggan But For AWP
1994	1	0.2439	0.1231	98.18%
1994	2	0.2438	0.1245	95.85%
1994	3	0.2374	0.1172	102.65%
1994	4	0.2476	0.1182	109.53%
1995	1	0.2383	0.1186	100.94%
1995	2	0.2184	0.1183	84.53%
1995	3	0.2257	0.1181	91.03%
1995	4	0.2204	0.1180	86.86%
1996	1	0.2184	0.1177	85.58%
1996	2	0.2088	0.1178	77.26%
1996	3	0.2242	0.1173	91.09%
1996	4	0.2252	0.1176	91.45%
1997	1	0.2376	0.1179	101.57%
1997	2	0.2159	0.1181	82.74%
1997	3	0.2386	0.1263	88.95%
1997	4	0.2418	0.1262	91.60%
1998	1	0.2378	0.1264	88.18%
1998	2	0.2285	0.1258	81.56%
1998	3	0.2354	0.1258	87.09%
1998	4	0.2277	0.1255	81.34%
1999	1	0.2503	0.1256	99.24%
1999	2	0.2274	0.1253	81.50%
1999	3	0.2465	0.1282	92.18%
1999	4	0.2547	0.1276	99.57%
2000	1	0.2527	0.1262	100.23%
2000	2	0.2283	0.1254	82.02%
2000	3	0.2408	0.1254	91.96%
2000	4	0.2436	0.1247	95.39%
2001	1	0.2127	0.1240	71.50%
2001	2	0.2204	0.1239	77.79%
2001	3	0.2415	0.1243	94.27%
2001	4	0.2342	0.1243	88.43%
2002	1	0.2143	0.1232	73.94%
2002	2	0.2343	0.1230	90.51%
2002	3	0.2322	0.1232	88.49%
2002	4	0.2310	0.1233	87.32%
2003	1	0.2121	0.1232	72.18%
2003	2	0.2221	0.1232	80.22%
2003	3	0.4538	0.2321	95.52%
2003	4	0.4792	0.2380	101.34%